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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/585,168	06/30/2006	Naohisa Kawamura	0003047USU/3019	9886
27623	7590	09/09/2010	EXAMINER	
OHLANDT, GREELEY, RUGGIERO & PERLE, LLP			KENNEDY, NICOLETTA	
ONE LANDMARK SQUARE, 10TH FLOOR			ART UNIT	PAPER NUMBER
STAMFORD, CT 06901			1611	
MAIL DATE		DELIVERY MODE		
09/09/2010		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/585,168	<b>Applicant(s)</b> KAWAMURA ET AL.
	<b>Examiner</b> Nicoletta Kennedy	<b>Art Unit</b> 1611

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If no period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 02 August 2010.  
 2a) This action is FINAL.      2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-5, 7, 10-13 and 15 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 1, 5-7, 10-13, 15 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) Notice of References Cited (PTO-892)  
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  
 3) Information Disclosure Statement(s) (PTO/SB/08)  
 Paper No(s)/Mail Date \_\_\_\_\_

4) Interview Summary (PTO-413)  
 Paper No(s)/Mail Date \_\_\_\_\_  
 5) Notice of Informal Patent Application  
 6) Other: \_\_\_\_\_

**DETAILED ACTION**

***Status of Claims***

Claims 1, 5-7, 10-13 and 15 are currently pending.

***Priority***

This application, filed June 30, 2006, is a national stage entry of PCT/JP2004/019078, filed December 21, 2004 and claims foreign priority to Japanese application 2004-011384, filed January 20, 2004. The International Bureau has provided a certified copy of the Japanese application.

***Withdrawn Objection***

1. The objection to claim 13 is withdrawn in view of Applicant's amendments.

***Modified Rejections Necessitated by Amendment***

***Claim Rejections - 35 USC § 103***

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. **Claims 1, 5-7 and 10-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hoffman et al. (US 5,254,348) (issued Oct. 19, 1993) in view of Spada et al. (US 5,185,212) (issued Feb. 9, 1993) and Wick (WO 86/06281) (pub. Nov. 6, 1986).**

Due to Applicant's amendment of the claims, the rejection is modified from the rejection as set forth in the Office action mailed March 1, 2010, as applied to claims 1, 5-7 and 9-13. Applicant's arguments filed August 2, 2010 have been considered but they are not persuasive. See below Response to Arguments.

The claims are drawn to a tulobuterol adhesive patch comprising, a release liner and a pressure-sensitive adhesive layer comprising a plasticizer.

Regarding claims 1 and 11-12, Hoffman et al. teach a tulobuterol patch comprising a backing layer (a support) and a pressure sensitive adhesive (column 1, 1<sup>st</sup> paragraph; column 4, line 5). Tulobuterol is contained within the adhesive mix (column 2, line 55). The patch also comprises a plasticizer (column 3, line 59). Hoffman et al. teach that 0.96 grams tulobuterol base are added to 60 grams of a pressure-sensitive adhesive solution, resulting in tulobuterol being present at 1.6% by weight (column 4, example 1). The solution is stirred until completely dissolved (column 4, example 1). However, Hoffman et al. fail to teach that the pressure sensitive adhesive is a copolymer of an acetoacetoxyalkyl (meth)acrylate and one or more vinyl monomers that are copolymerizable with the acetoacetoxyalkyl (meth)acrylate, wherein said vinyl monomer contains diacetoneacrylamide and/or tetraethyleneglycol dimethacrylate. Spada et al. and cure this deficiency.

Spada et al. teach that copolymers of acetoacetoxyalkyl (meth)acrylates and vinyl are useful as pressure-sensitive adhesives. The acetoacetoxyalkyl (meth)acrylate may be acetoacetoxyethyl methacrylate (column 5, line 29) Spada et al. further teach a number of vinyl monomers which may be incorporated into the polymer of its composition. Spada et al. teach a pressure-sensitive adhesive composition comprising acetoacetoxyethyl methacrylate, methacrylic acid and butyl acrylate (column 13, example 2). Spada et al. teach that the acetoacetoxyethyl methacrylate is present at 2.0% (column 13, example 2). MPEP 2144.05 states that "where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation" quoting *In re Aller*, 220 F.2d 454, 456, 105

USPQ 233, 235 (CCPA 1955). Spada et al. teach that increasing the amount of acetoacetoxyethyl methacrylate results in increased shear and it would have been *prima facie* obvious to a person of ordinary skill in the art to manipulate the amount of acetoacetoxyethyl methacrylate to find optimum or workable ranges. However, Spada et al. fail to teach that the vinyl monomer contains diacetoneacrylamide and/or tetraethyleneglycol dimethacrylate.

Wick teaches a pressure-sensitive adhesive tape comprising a reinforcing monomer such as methacrylic acid and diacetone acrylamide (abstract and p. 3, lines 30-37). Further, Wick teaches that ethyl oleate, a plasticizer, is present at 12% by weight of the formulation (p. 15, line 24).

It would have been *prima facie* obvious to a person of ordinary skill in the art at the time of the invention to have combined the teachings of Hoffman et al. with those of Spada et al. and Wick to arrive at the instant invention. One would have been motivated to substitute diacetone acrylamide for methacrylic acid in the example taught by Spada et al. because Wick teaches that both are reinforcing monomers used in pressure-sensitive adhesives. One would have been motivated to use the pressure-sensitive adhesive of Spada et al. and Wick in the transdermal patch of Hoffman et al. because the pressure-sensitive adhesive of Spada et al. and Wick is well known in the art and may be used in a transdermal patch with predictable, expected results.

Regarding claims 5-7, Wick teaches that isopropyl myristate is used in the pressure-sensitive adhesive tape formulation (p. 15, line 29).

Regarding claim 10, no water is present in the pressure-sensitive adhesive taught by the combination of Hoffman et al., Spada et al. and Wick (Spada et al., column 14, example 2).

**6. Claims 13 and are rejected under 35 U.S.C. 103(a) as being unpatentable over Hoffman et al. (US 5,254,348) (issued Oct. 19, 1993), Spada et al. (US 5,185,212) (issued Feb. 9, 1993) and Wick (WO 86/06281) (pub. Nov. 6, 1986) as applied to claims 1, 3, 5-12 and 14 above, and further in view of Kamiyama (US 6,632,906) (issued Oct. 14, 2003).**

Due to Applicant's amendment of the claims, the rejection is modified from the rejection as set forth in the Office action mailed March 1, 2010, as applied to claims 1, 5-7 and 9-13. Applicant's arguments filed August 2, 2010 have been considered but they are not persuasive. See below Response to Arguments.

The claims are drawn to a tulobuterol adhesive patch comprising, a release liner and a pressure-sensitive adhesive layer comprising a plasticizer. The pressure-sensitive adhesive layer is comprised of a particular copolymer.

Regarding claims 13, the combination of Hoffman et al., Spada et al. and Wick teach a tulobuterol adhesive patch with a pressure-sensitive adhesive comprising 2-acetoacetoxyethyl methacrylate, butyl methacrylate, and diacetone acrylamide. However, they fail to teach that the pressure-sensitive adhesive comprises 2-acetoacetoxyethyl methacrylate, diacetone acrylamide, tetraethyleneglycol dimethacrylate, 2-ethylhexyl acrylate and methylmethacrylate. Kamiyama cures this deficiency.

Kamiyama teaches an adhesive material suitable as a bioadhesive having good cohesion and low dermal irritation wherein 2-ethylhexyl acrylate, methyl methacrylate, butyl acrylate, diacetone acrylamide and tetraethyleneglycol dimethacrylate may be used to form adhesive of the invention (column 11, example 2, table 1 and table 1a). MPEP 2144.06 states that "[i]t is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art" quoting *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980). In the instant case, Hoffman et al., Spada et al. and Wick teach a tulobuterol adhesive patch with a pressure-sensitive adhesive comprising 2-acetoacetoxyethyl methacrylate, butyl methacrylate, and diacetone acrylamide.

It would have been *prima facie* obvious to a person of ordinary skill in the art at the time of the invention to have combine known adhesive copolymer components together to make a composition to be used for the very same purpose, as an adhesive material. One would have been motivated to do so because Spada et al. and Wick teach a basic pressure-sensitive adhesive composition and Kamiyama teach several more monomers that may be incorporated into an adhesive composition to result in good cohesion and low dermal irritation.

Regarding claim 15, the teachings of Hoffman et al., Spada et al., Wick and Kamiyama as set forth in the rejection under 35 U.S.C. 103(a) above, are hereby incorporated.

***Response to Arguments***

Applicant's arguments filed August 2, 1010 have been fully considered but they are not persuasive.

First, Applicant argues that quantitative data for the specific amounts provided in claim 1 are clearly demonstrated in tables 1-4. With regard to Table 1, each example shows tulobuterol at 10% by weight and provides no explanation or comparative results indicating why this 10% is superior to any other amount of tolobuterol. Nor are any data points above or below 10% supplied. With regard to Table 2, example 3 does show that tulobuterol is present at 3% but the results focus on the pressure sensitive adhesive, not the amount of tulobuterol. Further, the plaster weights are different and do not constitute a comparison that shows the effect of different amounts by weight of tulobuterol. With regard to Table 3, the same is true. With regard to Table 4, there are data points for 3% by weight tulobuterol but again, there is no data above or below the claimed range that indicates why this range is superior to other amounts. Further, as explained above, Hoffman et al. teach an amount of tulobuterol that lies within the claimed range. Similarly, the results in Tables 1-4 do not support the scope of the claimed ranges for the plasticizer nor for the acetoacetoxyalkyl (meth) acrylate. The plasticizer, specifically isopropyl myristate, is shown at 20% or 35%. The acetoacetoxyalkyl (meth) acrylate is shown as acetoacetoxyethyl methacrylate and is only shown as present in the pressure-sensitive adhesive production example (para. 0027). The purportedly unexpected results also do not compare the results with the closest prior art, Hoffman et al.

Therefore, the results are not commensurate in scope with the claims and do not compare the instant invention to the closest prior art.

Second, Applicant argues that Hoffman and Spada fail to disclose or suggest the use of 2-acetoacetoxyethyl methacrylate or 2-acetoacetoxyethyl acrylate. The examiner respectfully disagrees. As previously stated, Spada et al. teach that acetoacetoxyethyl methacrylate (AAEMA) and vinyl copolymers are useful as pressure-sensitive adhesives (column 5, line 29). 2-acetoacetoxyethyl methacrylate is equivalent to acetoacetoxyethyl methacrylate and was not previously disputed by Applicants in the remarks submitted June 1, 2010.

Finally, Applicant argues that combining the copolymer of Spada with the adhesive patch of Hoffman destroys the purpose of Hoffman because the copolymers of Spada increase adhesive strength. This supposition is not supported. Nothing in Hoffman teaches that pressure-sensitive adhesives should have minimal adhesive strength. In fact, Hoffman teach that self-adhesive properties to the skin are positive (column 7, lines 60-65).

It is suggested that the specific copolymer of dependent claim 13 be incorporated into claim 1, that claim 7 be incorporated into claim 1, that the calculation of how much acetoacetoxyethyl methacrylate is in the pressure sensitive adhesive in the instant specification examples be explained, and that the instant results be compared to Hoffman et al., specifically the styrene-1,3-diene-styrene block copolymer of Hoffman.

### ***Conclusion***

No claims are allowable.

All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nicoletta Kennedy whose telephone number is (571)270-1343. The examiner can normally be reached on Monday through Friday 11:30 to 8:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Gollamudi Landau can be reached on 571-272-0614. The fax

phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/N. K./  
Examiner, Art Unit 1611

/Anne R Kubelik/  
Primary Examiner, Art Unit 1638